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EDITORIAL COMMENT

Device Availability for the Child With Heart Disease*

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Although pediatric heart disease is the most common malformation in children in the first year of life, it remains quite uncommon when viewed through the lens of human disease as a whole. The frequency of most forms of congenital heart disease, <1 per 1,000 per lesion and <1 per 100 in aggregate, is dwarfed by the frequency of adult diseases such as coronary artery disease, cancer, gastric ulcer, and stroke. The relative rarity of pediatric heart diseases; the extreme difficulty in performing randomized controlled trials in children, who have issues around informed consent; and the relatively poor reimbursement rates for care delivered to children all have conspired to prevent the development of drugs or devices specifically designed to meet the needs of infants and children with heart disease. Recently, 2 devices have managed to overcome these multiple hurdles and obtain U.S. Food and Drug Administration approval for pediatric cardiac indication (1,2). The presence of an approved device for a limited indication would make efforts to approve any subsequent device even more difficult. However, the recent reports of late catastrophic erosions for one of the devices (3,4) highlights the importance of ongoing work to study new and improved designs for pediatric cardiac devices and then to obtain approval for those devices. For such work to succeed, the studies need to be well designed, carefully considered, compulsively executed, and self-critical.

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The study reported by Jones et al. (5) describing the use of the HELEX septal occluder (HSO) to close an atrial septal defect (ASD) percutaneously is one such trial. The indications for closure of an ASD have not been established with precision despite a half century of surgical experience. The consensus view that has emerged, however, seems reasonable; an ASD should be closed if there is clear noninvasive evidence of an enlarged, volume-loaded right ventricle. The HSO has a completely different design than either of the 2 devices approved for pediatric intracardiac use, the Amplatzer (AGA Medical, Golden Valley, Minnesota) or CardioSEAL (NMT Medical, Boston, Massachusetts). It has what appears to be the lowest profile of the 3 devices, and thus may produce the smallest amount of turbulence inside the heart. It is flexible, and thus should have very rare problems with late cardiac trauma. No intracardiac device is ideal, and the absence of an effective self-centering mechanism for the HELEX occluder may result in a higher incidence of small residual leaks in certain patients. However, the addition of this device to the armamentarium of cardiologists taking care of children is a welcome one. Perhaps more importantly, the method used by the investigators to get through the regulatory and commercial hurdles of device approval can, and should, serve as a model for others seeking to improve the care of children with heart disease.

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